An electronic drug record for every American

A - Purpose:

1. Develop a "straw person" set of alternative critical paths to an electronic drug record for every American for discussion by CSI
2. Use this relatively simple example to illustrate for CSI what a time line for adoption of health care information technology standards might look like, and how choices might influence rate at which benefit is achieved.

B - Task:

1. Depict as a time line with key benefit milestones; decision points; dates where compliance with standards or adoption of a technology are required to achieve benefit; and dates where a benefit reaches the point where progress is self sustaining.

C - Rules of engagement:

1. We do not need to get it right. We need a plausible path.
2. Represent key branch points as decisions, even if we flesh out only one branch.
3. Decompose the problem into steps. Each should provide benefit and a foundation for successive steps. Exclude non-essentials from a step if they extend the critical path.

D – Process used to develop the critical path:

1. Develop use cases to depict various potential views of an electronic drug record
2. Organize use cases into a framework to show logical groups of functionality
3. Subdivide use cases into steps where one step provides both benefit and a foundation for subsequent steps
4. Sequence use cases to reflect readiness and dependencies.

*** At this point, we have a view of what an electronic drug record will become, a potential sequence in which function might be provided.

5. Select a subset of use case/use case steps that appear to provide a reasonable path to the ultimate objective
6. Identify information sources, standards, and governance/infrastructure required for each use case/use case steps
7. Identify the major decisions needed for each use case/use case steps
8. Identify the types of benefit and risk of each use case/use case steps

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*** At this point, we know the information we need to assemble a time line.

9. Estimate the elapsed time required for each item in #6, according to different outcomes of decisions in #7.
10. Estimate the $, safety, quality, convenience benefit for each use case
11. Depict as a time line

E – Use cases:

I. Personal drug list

a. Each person, or their health coach, keeps a list of their medicines on a personal device. Entry of the drug name, NDC, or other identifier from their drug bottle fills in basic information from a server at the National Library of Medicine and provides links to the FDA electronic label and other information. The person can print the list, carry it with them. They can give it to their providers either on paper or via their key fob.
b. The program checks for interactions against other drugs on the list.
c. A web-based application provides the above functionality.
d. Additional functionality lets the person delegate access, import updates from their pharmacy, or upload the list to their physician.

II. List of drugs dispensed to a person

a. The medication name, dose form and dose amount of all drugs dispensed for a person are aggregated in a web accessible data base. Naming terminology is not standardized. The lists are available for review by patients and providers. The same drug may appear multiple times if the dispensing sources use different terminology. Computerized interaction checking and other forms of computerized decision support are not possible. Patients are notified about product withdrawals if the dispensing entity chooses to do so, but no coordination of notification (e.g., in the event a patient switches plans) is possible.
b. The above functionality is provided for drugs using standardized naming terminologies. Interactions are checked across providers and plans. Patients are notified about product withdrawals both directly by the dispensing entity and if they elect, by other entities authorized to do so, etc. Providers know what the patient has received.

III. Computer-based order entry and electronic prescribing

a. Care providers use computer tools as they make prescribing decisions. These tools use information from the electronic list of dispensed medicines, best practice guidelines and insurance formularies to guide decisions. Decisions are individualized and evidence based.

IV. Post market surveillance

a. Records of drugs dispensed to a patient, together with information about diagnoses and tests from their medical record, are systematically monitored to identify expected and unexpected side effects.

F: Benefit building up over time:

Use Case	**Benefit Type**	**Benefit Amount**
I a	Patient has the list and easy access to information about the drugs, increasing their understanding & comfort Reduced adverse drug events, tier 1 Patient can hand the provider the list instead of having to remember and relay the information	
I b	Reduced adverse drug events, tier 2 (programmed checking)	
I c	Information is available to the patient any time any place	
II b	Patient does not have to do data entry Decreased prescriptions (all providers see complete list) Reduced adverse drug events, tier 3 (drug list is more complete) Improved effectiveness (provider knows if prescription was filled)	
III	Better drug choices Reduced adverse drug events, tier 4 (allergies)	
IV	Post market detection of unexpected adverse events	

Note: We did not do further work on Use Cases I d and II a. At high level, I d appears to require much of the infrastructure of II b with less benefit. Although a II a approach will likely be required for many types of health information, it does not appear to be necessary for drugs since a clear semantic model is within near term reach.

G: Required standards, governance, infrastructure

Use Case	Source	Standards	Governance/Infrastructure
I a	Patient entry	1. RxNorm semantic clinical drug name (aspirin 325 mg tablet); & identifier; (available in useable form) 2. FDA electronic label (SPL2 passed HL7 ballot May 05)	1. National Library of Medicine (NLM) RxNorm server to allow an application to submit a drug name or ID and retrieve related information. 2. FDA submission of electronic label to NLM, (scheduled to start 10/05 and be relatively complete 10/06) 3. NLM "daily med" to link FDA updates to RxNorm and distribute for incorporation into applications 4. PC & handheld applications adapted to use RxNorm
I b		3. Drug interaction representation (Can be accommodated in SPL2)	5. Publicly accessible drug-drug interaction knowledge base
I c			6. Personal authentication mechanism & Web based application and hosting service (such as Medem announced 5/9/05) adapted to use RxNorm.
II b	Adjudication Claims Retail pharmacy	4. Messaging standard (Outbound from dispensing systems to drug record) 5. Patient ID data set (minimum for linkage) 6. Submitter ID data set (Who dispended) 7. Subset of Dispensing data (minimum to build drug record) 8. Role & team definitions to support authorization on a need to know basis	7. Retrofit source systems for messaging standards 8. Well maintained map between NDC (product label) & RxNorm sematic model (drug substance, dose form, strength) 9. Mechanism to resolve patient identity 10. Patient index, switch, and drug record repository infrastructure 11. Governance and technology to support authentication across systems 12. Governance and technology for team & role based authorization
III		9. Message standard (inbound to point of care systems) 10. Allergy standard 11. Reaction standard	13. Point of care E-prescribing & CPOE 14. Retrofit above for RxNorm & messaging standards
IV	Providers		15. Deidentified records with dispensed drugs, allergies, diagnoses, labs

H: Decisions that affect the critical path

Use Case	Decision	Options
I a	1. **PC application** – How should we provide ubiquitous access to a PC application that uses RxNorm to link in relevant information?	a. Require personal health record vendors to use RXNorm b. Source a downloadable application from the NLM c. Both a & b
I c	2. **Source for drug drug interactions** – How do we provide public access to a drug drug interaction database? *****CSI recommendations should include c*****	a. License from FDB, Multum, etc b. Find in public domain c. Expedite FDA plans to develop & maintain interaction database as a by-product of electronic labeling. d. Either (a or b) plus c
II b	3. **Source of dispensing data** – Which sources of dispensing data are needed to build a complete drug record?	a. Claims b. PBMs at time of adjudication c. Pharmacies d. All of the above
II b	4. **Dispensing Messaging standard (outbound)** – Should we pick the semantic model (HL7), the dispensing model (Script) or support both through mapping?	a. HL7 or NCPDP Script b. HL7 & NCPDP Script
II b	5. **RxNorm assigned with NDC** – Where should RxNorm be mapped to NDC? *****CSI recommendations should include both a&b*****	a. RXNorm ID is assigned at the same time as NDC and submited with electronic label b. FDA maintains database of all NDC
II b	6. **Mechanism to resolve pt identity** – What identification data will be used to merge entries about a patient into a consolidated list?	a. National patient identifier b. Patients opt in to a patient identifier to be have an electronic drug list c. Plans resolve identifier set on transfer of patient between plans d. Combination of b&c
II b	7. **Submitter ID** – What # should be used to identify the dispenser who is submitted the data?	a. Require use of freely available DUNS number (Dunn & Bradstreet) b. Establish national provider identifier & extend to include all entities involved in dispensing
II b	8. **Patient index, switch, & drug record repository infrastructure** – How do we provide the shared infrastructure to aggregate, maintain and provide secure access to the drug list?	a. Build with components from Federal Health Information Exchange (FHIE) b. Nationalize one of the competing hubs (RxHub, BlueCross/Cerner, SureScripts c. Require all of the above to implement the standards & implement a back end aggregation database & authentication/authorization

		infrastructure
II b	9. **Authentication & Authorization Governance & technical approach** – When someone wants to access a drug list, how do we decide if they are who they say they are and if they have a valid reason to access information about a specific patient?	a. National service b. Shared responsibility c. Standards based interoperable applications